Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/09/02 08/24/04 04/11/02 04/15/03 02/04/03	728 730 728 730 728	50(1) 50(1) 50(1) 50(1) 50(1)	39(688) 34(689) 34(692) 38(691) 35(702)	56.7 56.4 56.2 56.6 52.7	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene
					Female		
Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/08/02 08/23/04 04/10/02 04/14/03 02/03/03	727 729 727 729 731	49(5) 50(5) 50(5) 49(5) 50(5)	34(679) 38(695) 39(705) 35(705) 35(675)	65.0 66.2 64.1 64.9 63.2	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
#All Organs: Benign Tumors								
		33/50 (66%) 30/50 (60%)	34/50 (68%) 30/50 (60%)	33/50 (66%)		20/49 (41%) 27/49 (55%)	26/50 (52%) 24/50 (48%)	21/50 (42%)
Overall Incidence	Total	160/250 (64%)	Mean 64%	SD 3.74%	Total	118/248 (47.58%)	Mean 47.58%	SD 6.19%
#All Organs: Malignant Tumors								
		20/50 (40%) 19/50 (38%)	32/50 (64%) 28/50 (56%)	30/50 (60%)		21/49 (43%) 20/49 (41%)	19/50 (38%) 13/50 (26%)	14/50 (28%)
Overall Incidence	Total	129/250 (51.6%)	Mean 51.6%	SD 11.87%	Total	87/248 (35.08%)	Mean 35.13%	SD 7.66%
#All Organs: Malignant and Benign To								
		43/50 (86%) 38/50 (76%)	47/50 (94%) 41/50 (82%)	43/50 (86%)		34/49 (69%) 40/49 (82%)	39/50 (78%) 29/50 (58%)	30/50 (60%)
Overall Incidence	Total	212/250 (84.8%)	Mean 84.8%	SD 6.57%	Total	172/248 (69.35%)	Mean 69.4%	SD 10.51%
#All Organs: Hemangioma								
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	4/248 (1.61%)	Mean 1.61%	SD 1.68%
#All Organs: Hemangiosarcoma								
		3/50 (6%) 3/50 (6%)	6/50 (12%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 3/49 (6%)	1/50 (2%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	22/250 (8.8%)	Mean 8.8%	SD 3.9%	Total	6/248 (2.42%)	Mean 2.43%	SD 2.24%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Route: GAVAGE

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Strain: B6C3F1 Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
#All Organs: Hemangiosarcoma or F	lemangioma							
		3/50 (6%) 3/50 (6%)	8/50 (16%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 4/49 (8%)	1/50 (2%) 1/50 (2%)	3/50 (6%)
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 4.98%	Total	10/248 (4.03%)	Mean 4.04%	SD 2.88%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 3/49 (6%)	3/50 (6%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	7/248 (2.82%)	Mean 2.82%	SD 3.07%
Overall Incidence	Total	0/50 (0%) 1/50 (2%) 5/250 (2%)	2/50 (4%) 1/50 (2%) Mean 2%	1/50 (2%) SD 1.41%	Total	11/49 (22%) 6/49 (12%) 32/248 (12.9%)	6/50 (12%) 2/50 (4%) Mean 12.94%	7/50 (14%) SD 6.57%
		(/						
	M-11 NOC							
#All Organs: Mesothelioma: Benign,	Malignant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Mesothelioma: Benign,	Malignant, NOS	0/50 (0%)	` ,	0/50 (0%) SD 0%	Total	()	` ,	0/50 (0%) SD 0%
Mesothelioma: Benign, Overall Incidence	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	, ,	Total	0/49 (0%)	0/50 (0%)	,
Mesothelioma: Benign, Overall Incidence #All Organs:	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	, ,	Total	0/49 (0%)	0/50 (0%)	,

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#All Organs: Osteosarcoma or Oste								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Adrenal Cortex:				•••••				•••••
		3/50 (6%)	0/50 (0%)	2/50 (4%)		0/48 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/50 (2%) 9/250 (3.6%)	3/50 (6%) Mean 3.6%	SD 2.61%	Total	1/49 (2%) 2/246 (0.81%)	0/49 (0%) Mean 0.81%	SD 1.11%
Adrenal Cortex: Plasma Cell Tumor Mal	lignant							
	J	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/246 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	enign							
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma	alignant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%
Adrenal Medulla: Pheochromocytoma: B	enign, Complex	, Malignant, NOS						
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/246 (0.81%)	Mean 0.82%	SD 1.12%
*Bone Marrow: Hemangioma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/247 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** *Bone Marrow: Hemangiosarcoma 0/50 (0%)2/50 (4%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)1/247 (0.4%) Overall Incidence Total 2/250 (0.8%) Mean 0.8% SD 1.79% Total Mean 0.41% SD 0.91% *Bone Marrow: **Plasma Cell Tumor Malignant** (0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/48 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/247 (0%) Mean 0% SD 0% #Bone: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% #Bone: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% #Bone: Osteosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/49 0/50 (0%)0/50 (0%)

SD 0%

0/49

1/248 (0.4%)

Total

(0%)

0/50

(0%)

SD 0.91%

Mean 0.41%

Total

0/50

0/250 (0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female	
#Bone: Osteosarcoma or Osteoma	ı							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maliç	ınant, NOS							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/241 (0.41%)	Mean 0.41%	SD 0.91%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/241 (0.41%)	Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/241 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 12

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
#Esophagus: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		8/50 (16%) 6/50 (12%)	5/50 (10%) 6/50 (12%)	9/50 (18%)		3/49 (6%) 7/49 (14%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
Overall Incidence	Total	34/250 (13.6%)	Mean 13.6%	SD 3.29%	Total	33/248 (13.31%)	Mean 13.28%	SD 8.77%
#Harderian Gland: Carcinoma								
		4/50 (8%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		1/49 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 3.29%	Total	2/248 (0.81%)	Mean 0.82%	SD 1.12%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

: Marzuru

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%) 7/50 (14%)	5/50 (10%) 6/50 (12%)	9/50 (18%)		4/49 (8%) 8/49 (16%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
verall Incidence	Total	39/250 (15.6%)	Mean 15.6%	SD 5.55%	Total	35/248 (14.11%)	Mean 14.1%	SD 8.48%
Harderian Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Heart: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
fIntestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 15

			Male				Female	
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female	
#Intestine Small: Jejunum: Adenoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total 1/248 (0.4%)	Mean 0.4% SD 0.89%	
#Intestine Small: Jejunum: Carcinoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0% 2/50 (4%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2% SD 1.79%	Total 1/248 (0.4%)	Mean 0.4% SD 0.89%	
#Intestine Small: Jejunum: Hemangiosarcoma						
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total 0/248 (0%)	Mean 0% SD 0%	
#Intestine Small: Jejunum: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%	
#Intestine Small: Site Unspec Adenoma						
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79%	Total 2/248 (0.81%)	Mean 0.8% SD 1.79%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

			Male				Female	
#Intestine Small: Site Uns Carcinoma	specified:							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Uns Carcinoma or Adenoma	•							
		0/50 (0%) 0/50 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.83%	Total	3/248 (1.21%)	Mean 1.2%	SD 1.79%
Intestine Small: Site Uns Hemangiosarcoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Leiomyosarcoma	specified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
fintestine Small: Site Uns Polyp Adenomatous	specified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 18 Report Date: 03/22/2010

Mean 0.41%

Mean 0%

(0%)

(0%)

0/50

0/49

SD 0.91%

SD 0%

(0%)

0/50

			Male				Female	
*Islets, Pancreatic: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	3/245 (1.22%)	Mean 1.22%	SD 1.82%
*Kidney: Renal Tubule: Adenoma		•••••						
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)

SD 1.1%

0/50

SD 0%

(0%)

Total

Total

1/245 (0.41%)

(0%)

(0%)

0/47

0/49

0/245 (0%)

Total

Total

3/250 (1.2%)

0/50

0/50

0/250 (0%)

(0%)

(0%)

Mean 1.2%

(0%)

(0%)

0/50

0/50

Mean 0%

Overall Incidence

Overall Incidence

*Kidney: Renal Tubule: Carcinoma

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Kidney: Renal Tubule: Hemangioma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligi	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: GAVAGE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Vehicle: CORN OIL

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			Male				Female	
Liver: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
_iver: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
		0/230 (0/0)				0/247 (0 /0)		
Liver: Hemangiosarcoma								
		1/50 (2%)	5/50 (10%)	5/50 (10%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 12/250 (4.8%)	1/50 (2%) Mean 4.8%	SD 4.82%	Total	0/49 (0%) 1/247 (0.4%)	0/49 (0%) Mean 0.4%	SD 0.89%
	10tai	12/230 (4.676)	4.0 /6			1/247 (0.476)		
Liver: Hepatoblastoma								
		3/50 (6%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	4/50 (8%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	10/250 (4%)	Mean 4%	SD 3.16%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
•		24/50 (48%) 22/50 (44%)	27/50 (54%) 22/50 (44%)	26/50 (52%)		11/49 (22%) 13/49 (27%)	8/50 (16%) 3/49 (6%)	6/50 (12%)
Overall Incidence	Total	121/250 (48.4%)	Mean 48.4%	SD 4.56%	Total	41/247 (16.6%)	Mean 16.62%	SD 8.13%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male				Female	
Liver: Hepatocellular Carcino	ma							
		8/50 (16%) 13/50 (26%)	20/50 (40%) 17/50 (34%)	14/50 (28%)		3/49 (6%) 5/49 (10%)	3/50 (6%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	72/250 (28.8%)	Mean 28.8%	SD 9.01%	Total	14/247 (5.67%)	Mean 5.68%	SD 3.04%
*Liver: Hepatocellular Carcino	ma or Hepatobl	lastoma						
•		11/50 (22%) 13/50 (26%)	20/50 (40%) 19/50 (38%)	16/50 (32%)		3/49 (6%) 5/49 (10%)	3/50 (6%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	79/250 (31.6%)	Mean 31.6%	SD 7.67%	Total	14/247 (5.67%)	Mean 5.68%	SD 3.04%
*Liver: Hepatocellular Carcinol Overall Incidence	ma or Hepatoce	ellular Adenoma 28/50 (56%) 29/50 (58%) 162/250 (64.8%)	38/50 (76%) 34/50 (68%) Mean 64.8%	33/50 (66%) SD 8.07%	Total	13/49 (27%) 17/49 (35%) 51/247 (20.65%)	10/50 (20%) 4/49 (8%) Mean 20.68%	7/50 (14%) SD 10.4%
Liver: Henatocellular Carcino	ma Henatocelli	ular Adenoma, or Hepatok	olastoma					
riopatoconaia: caronio	ma, riopatocom	30/50 (60%) 29/50 (58%)	38/50 (76%) 34/50 (68%)	34/50 (68%)		13/49 (27%) 17/49 (35%)	10/50 (20%) 4/49 (8%)	7/50 (14%)
		20/00 (00/0)	, ,					
Overall Incidence	Total	165/250 (66%)	Mean 66%	SD 7.21%	Total	51/247 (20.65%)	Mean 20.68%	SD 10.4%
		165/250 (66%)			Total			
Overall Incidence *Liver: Hepatocholangiocarcin		` ,	Mean 66% 4/50 (8%) 1/50 (2%)	SD 7.21% 	Total	51/247 (20.65%) 0/49 (0%) 0/49 (0%)	Mean 20.68% 0/50 (0%) 0/49 (0%)	SD 10.4% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 22

			Male				Female	
Liver: Hepatocholangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Malignan								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Plasma Cell Tumor Mali	gnant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 23 Report Date: 03/22/2010

			Male				Female	
*Lung: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A	denoma							
		6/50 (12%) 6/50 (12%)	9/50 (18%) 5/50 (10%)	8/50 (16%)		4/48 (8%) 1/49 (2%)	2/50 (4%) 3/49 (6%)	4/50 (8%)
Overall Incidence	Total	34/250 (13.6%)	Mean 13.6%	SD 3.29%	Total	14/246 (5.69%)	Mean 5.7%	SD 2.68%
Lung: Alveolar/Bronchiolar C								
		2/50 (4%) 3/50 (6%)	2/50 (4%) 3/50 (6%)	5/50 (10%)		0/48 (0%) 2/49 (4%)	2/50 (4%) 0/49 (0%)	2/50 (4%)
Overall Incidence	Total	15/250 (6%)	Mean 6%	SD 2.45%	Total	6/246 (2.44%)	Mean 2.42%	SD 2.21%
Lung: Alveolar/Bronchiolar C	arcinoma or Alv	veolar/Bronchiolar Adeno	ma					
		7/50 (14%) 9/50 (18%)	11/50 (22%) 7/50 (14%)	13/50 (26%)		4/48 (8%) 3/49 (6%)	4/50 (8%) 3/49 (6%)	6/50 (12%)
Overall Incidence	Total	47/250 (18.8%)	Mean 18.8%	SD 5.22%	Total	20/246 (8.13%)	Mean 8.12%	SD 2.4%
Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 24

			Male				Female	
Lung: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malig								
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data M

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 25

			Male				Female	
Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node: Plasma Cell Tumor Malig								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
#Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Malignar	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
#Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Mammary Gland: Adenoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/248 (0.4%)	0/50 (0%) Mean 0.41%	SD 0.91%
#Mammary Gland: Carcinoma or Adenoma	a							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Fibroadenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	Adenoma						
·	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29 Report Date: 03/22/2010

			Male				Female	
#Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mesentery: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
fMesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 30

			Male				Female	
Oral Cavity (Oral Mucos Papilloma Squamous o	. •	ynx, Tooth, Gingiva):						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Squamous Cell Carcing	sa, Tongue, Phar	ynx, Tooth, Gingiva):						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Squamous Cell Carcino	oma, Papilloma S	Squamous, or Papilloma 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Squamous Cell Carcino	oma, Papilloma 🤄	-						
	oma, Papilloma S	-	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%	Total	0/49 (0%) 0/49 (0%) 0/248 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall Incidence 		0/50 (0%) 0/50 (0%)	0/50 (0%)	,	Total	0/49 (0%)	0/50 (0%)	,
Squamous Cell Carcing Overall Incidence *Ovary: Choriocarcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	,	Total	0/49 (0%)	0/50 (0%)	,
Overall Incidence *Ovary: Choriocarcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	,	Total Total	0/49 (0%) 0/248 (0%) 0/48 (0%)	0/50 (0%) Mean 0% 0/49 (0%)	SD 0%
Overall Incidence *Ovary: Choriocarcinoma Overall Incidence		0/50 (0%) 0/50 (0%)	0/50 (0%)	,		0/49 (0%) 0/248 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/49 (0%) 0/49 (0%)	SD 0% 0/50 (0%)
Overall Incidence *Ovary: Choriocarcinoma Overall Incidence *Ovary:		0/50 (0%) 0/50 (0%)	0/50 (0%)	,		0/49 (0%) 0/248 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/49 (0%) 0/49 (0%)	SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
*Ovary: Fibrous Histiocytoma				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
	I Olal	` '		
*Ovary: Granulosa Cell Tumor Benign				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Insidence	Total	1/49 (2%)	0/49 (0%)	CD 0.040/
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Ovary: Granulosa Cell Tumor Malignant				
-		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
g.,g.,,		0/48 (0%)	0/49 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Ovary: Hemangioma				
		0/48 (0%) 1/49 (2%)	0/49 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.82%	SD 1.12%
		• •		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 32

Male			Female	
Ovary:				
Hemangiosarcoma				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	00.000
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
Ovary: Leiomyosarcoma				
•		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	. ,
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
			•••••	
Ovary: Luteoma				
		0/48 (0%)	1/49 (2%)	1/50 (2%)
		0/49 (0%)	0/49 (0%)	
overall Incidence	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%
Ovary: Plasma Cell Tumor Malignant				
•		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	,
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Benign				
•		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	1/49 (2%)	. ,
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 33

			Male				Female	
Ovary: Teratoma Malignant								
						0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence					Total	0/245 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
						0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence					Total	0/245 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/244 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Species: MICE
Strain: B6C3F1

Route: GAVAGE Vehicle: CORN OIL **Page:** 34

			Male				Female	
Pituitary Gland: Pars Dis Adenoma	stalis or Unspeci	fied Site:						
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		4/47 (9%) 2/49 (4%)	2/50 (4%) 1/49 (2%)	1/50 (2%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.13%	SD 2.65%
*Pituitary Gland: Pars Dis Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma or Adenom	•		0/49 (0%)	0/49 (0%)		4/47 (Q9/L)	2/50 (4%)	1/50 (2%)
*Pituitary Gland: Pars Dis	•	0/50 (0%)	0/49 (0%)	0/49 (0%)		4/47 (9%)	2/50 (4%)	1/50 (2%)
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence	a Total		0/49 (0%) 0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	4/47 (9%) 2/49 (4%) 10/245 (4.08%)	2/50 (4%) 1/49 (2%) Mean 4.13%	1/50 (2%) SD 2.65%
*Pituitary Gland: Pars Dis	a Total	0/50 (0%) 0/50 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	2/49 (4%) 10/245 (4.08%)	1/49 (2%) Mean 4.13%	SD 2.65%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Int	a Total	0/50 (0%) 0/50 (0%)	0/49 (0%)	(,	Total	2/49 (4%)	1/49 (2%)	,
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence 	Total eermedia:	0/50 (0%) 0/50 (0%) 0/247 (0%) 0/50 (0%) 0/50 (0%) 1/247 (0.4%)	0/49 (0%) Mean 0% 1/49 (2%)	SD 0%	Total Total	2/49 (4%) 10/245 (4.08%) 0/47 (0%)	1/49 (2%) Mean 4.13% 1/50 (2%)	SD 2.65%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Int Adenoma	Total termedia: Total termedia:	0/50 (0%) 0/50 (0%) 0/247 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) Mean 0% 1/49 (2%) 0/49 (0%)	SD 0% 0/49 (0%)		2/49 (4%) 10/245 (4.08%) 0/47 (0%) 0/49 (0%)	1/49 (2%) Mean 4.13% 1/50 (2%) 0/49 (0%)	SD 2.65% 0/50 (0%)
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Int Adenoma Overall Incidence	Total termedia: Total termedia:	0/50 (0%) 0/50 (0%) 0/247 (0%) 0/50 (0%) 0/50 (0%) 1/247 (0.4%)	0/49 (0%) Mean 0% 1/49 (2%) 0/49 (0%)	SD 0% 0/49 (0%)		2/49 (4%) 10/245 (4.08%) 0/47 (0%) 0/49 (0%)	1/49 (2%) Mean 4.13% 1/50 (2%) 0/49 (0%)	SD 2.65% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
*Prostate: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male				Female	
Salivary Glands: Mast Cell Tumor Malignan	t							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
≇Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Myxosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)		SD 0.89%	Total	5/248 (2.02%)	Mean 2%	SD 2.83%
#Skeletal Muscle: Rhabdomyosarcoma or								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)		SD 0.89%	Total	5/248 (2.02%)	Mean 2%	SD 2.83%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benign					•••••	
	·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin:		umor Benign, or Trichoe						
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
#Skin: Basal Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Carcinoma	or Basosquamou	o/50 (0%) 0/50 (0%) 0/50 (0%)	NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tu 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
NOS), or Trichoepitheli		•	, , ,		Total	0/49 (0%) 0/49 (0%) 1/248 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%)	0/50 (0%)	,
NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%)	0/50 (0%)	,
NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%)	0/50 (0%) SD 0% a ,		0/49 (0%) 1/248 (0.4%) 0/49 (0%)	0/50 (0%) Mean 0.4% 	SD 0.89%
NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% a, 0/50 (0%)		0/49 (0%) 1/248 (0.4%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0.4% 	SD 0.89% 1/50 (2%)
NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% a, 0/50 (0%)		0/49 (0%) 1/248 (0.4%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0.4% 	SD 0.89% 1/50 (2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Skin: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin:		oma, Myxosarcoma, or Fi		•••••				
·	, , , ,	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		3/49 (6%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	8/248 (3.23%)	Mean 3.24%	SD 2.33%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/248 (1.21%)	Mean 1.21%	SD 1.1%
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	ı, or Fibrous Histiocytoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		3/49 (6%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	8/248 (3.23%)	Mean 3.24%	SD 2.33%
#Skin: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: GAVAGE Strain: B6C3F1

Length of Study: CHRONIC

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Report Date: 03/22/2010

Vehicle: CORN OIL

			Male				Female	
#Skin: Granular Cell Tumor Ben	nign							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
∕Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
∜Skin: Hemangiosarcoma								
_		1/50 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 4/250 (1.6%)	1/50 (2%) Mean 1.6%	SD 0.89%	Total	0/49 (0%) 2/248 (0.81%)	0/50 (0%) Mean 0.81%	SD 1.11%
#Skin: Liposarcoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skin: Mast Cell Tumor Benign								
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC **Toxicology Data Management System**

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female			
#Skin: Myxosarcoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%		
Skin: Neurofibrosarcoma or	Schwannoma (m	nalignant or NOS)								
	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.82%		
#Skin: Neurofibrosarcoma, N Overall Incidence	eurofibroma, or \$ Total	Schwannoma (benign, ma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 2/49 (4%) 3/248 (1.21%)	0/50 (0%) 1/50 (2%) Mean 1.22%	0/50 (0%) SD 1.82%		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
Skin: Osteosarcoma	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	1/50 (2%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/49 (0%) 0/49 (0%) 0/248 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin: Osteosarcoma Overall Incidence	Total	0/50 (0%)	0/50 (0%)	, ,	Total	0/49 (0%)	0/50 (0%)	(3.2.2)		
#Skin: Osteosarcoma Overall Incidence #Skin:	Total	0/50 (0%)	0/50 (0%)	, ,	Total	0/49 (0%)	0/50 (0%)	(3.2.2)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 42

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.82%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	•	` •	,		0/49 (0%)	0/50 (0%)	0/50 (0%)
	, Basal Cell C Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	or NOS), 0/50 (0%) SD 0%	Total	0/49 (0%) 0/49 (0%) 0/248 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
or Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%) 0/248 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)		0/49 (0%) 0/248 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 1/50 (2%)	SD 0% 0/50 (0%)
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)		0/49 (0%) 0/248 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 1/50 (2%)	SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 43

			Male				Female	
#Skin: Squamous Cell Papilloma	, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0)%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papilloma			0/50 (0%) 0/50 0/50 (0%)) (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD ()%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Trichoepithelioma				•••••				
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0)%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD (Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD ()%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 44

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
'Spleen: Hemangiosarcoma								
-		0/50 (0%) 2/50 (4%)	2/50 (4%) 2/50 (4%)	1/49 (2%)		1/48 (2%) 1/49 (2%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	7/249 (2.81%)	Mean 2.81%	SD 1.78%	Total	2/244 (0.82%)	Mean 0.82%	SD 1.13%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL mal Groups Report Date: 03/22/2010

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			Male				Female	
Spleen: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/244 (0.41%)	Mean 0.41%	SD 0.91%
*Spleen: Plasma Cell Tumor Malignaı								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
-	-	0/50 (0%) 1/50 (2%)	9/50 (18%) 1/50 (2%)	0/50 (0%)		1/49 (2%) 2/49 (4%)	3/50 (6%) 2/50 (4%)	1/50 (2%)
Overall Incidence	Total	11/250 (4.4%)	Mean 4.4%	SD 7.67%	Total	9/248 (3.63%)	Mean 3.62%	SD 1.67%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 46

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	8/50 (16%) 1/50 (2%)	0/50 (0%)		1/49 (2%) 2/49 (4%)	3/50 (6%) 2/50 (4%)	1/50 (2%)
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 6.99%	Total	9/248 (3.63%)	Mean 3.62%	SD 1.67%
#Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
Testes: Adenoma								
		2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%				
*Thymus: Thymoma Benign								
-		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 47

			Male				Female	
Thymus: Thymoma Malignant								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Ce Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/246 (0.81%)	Mean 0.81%	SD 1.11%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 48 Report Date: 03/22/2010

			Male				Female	
Thyroid Gland: Follicular Carcinoma	Cell:							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	3/246 (1.22%)	Mean 1.22%	SD 1.83%
*Thyroid Gland: Follicular Carcinoma or Adenoma	Cell:							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 2/49 (4%)	0/50 (0%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	5/246 (2.03%)	Mean 2.03%	SD 2.04%
#Tissue NOS: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maliç	gnant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 49

			Male				Female	
#Tissue NOS: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	na or Papillom	a Squamous						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma	a							
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 03/22/2010

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Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Mali	ignant							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 03/22/2010

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% **#Uterus:** Carcinoma (0%) 0/49(0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Uterus: Hemangiosarcoma 0/49 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Uterus: Leiomyoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)

Total

0/248 (0%)

.....

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC Route: GAVAGE Vehicle: CORN OIL **Page:** 52

	Male		Female	
#Uterus: Leiomyosarcoma				
		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Tota	- ()	Mean 0%	SD 0%
#Uterus: Polyp Stromal				
		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Tota	al 2/248 (0.81%)	Mean 0.8%	SD 1.79%
#Uterus: Sarcoma Stromal				
		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Tota	al 1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Uterus: Sarcoma Stromal or Polyp Stromal				
		1/49 (2%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Tota	al 3/248 (1.21%)	Mean 1.21%	SD 1.79%
#Uterus: Schwannoma Malignant				
		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Tota		Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 53

Male			Female		
#Vagina: Liposarcoma		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	
#Vagina: Squamous Cell Papilloma		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied